Attorney Docket No.:

270/175US (UMD-0060) DiCicco-Bloom et al.

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REMARKS

Claims 46-49 are pending in this application and have been subjected to a Restriction Requirement under 35 U.S.C. §121 as follows:

Group I, claim 46, drawn to in vitro methods of modulating cell growth;

Group II, claim 46, drawn to *in vivo* methods of modulating cell growth;

Group III, claim 47, drawn to methods of promoting proliferation of neuronal precursor cells by administering nucleic acids;

Group IV, claim 47, drawn to *in vitro* methods of promoting proliferation of neuronal precursor cells other than by administering nucleic acids;

Group V, claim 47, drawn to *in vivo* methods of promoting proliferation of neuronal precursor cells other than by administering nucleic acids;

Group VI, claims 48 and 49, drawn to methods of treating medical conditions caused by aberrant growth and increasing brain tissue by administering PAC_1 ligand or antagonist thereby increasing cell growth or proliferation; and

Group VII, claim 48, drawn to methods of treating medical conditions caused by aberrant growth by administering a PAC_1 ligand, thereby decreasing cell growth or proliferation.

The Examiner suggests that the inventions listed as Groups I-VII are unrelated because the methods of Inventions I and IV are to be performed *in vitro*, whereas the methods of Inventions II and V-VII are drawn to *in vivo* treatments. It is suggested that Inventions I and II are distinct and independent because the

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two methods require different starting materials. Likewise, it is suggested that Invention I is distinct from Invention IV because the two methods have different starting materials and goals; Invention I requires the use of a PAC1 ligand and Invention IV can use other compounds. Invention II is suggested as being distinct from Invention V because the methods require different starting materials; Invention II requires the use of a PAC1 ligand and Invention V requires the use of a compound that decreases the expression of PACAP in a cell. Invention III is suggested as being distinct from all other invention because Invention III requires the use of nucleic acids, which are not required as starting materials for any of the other methods. The Examiner suggests that Invention V is distinct and independent from Inventions VI and VII because the methods have different steps and goals. It is suggested that Inventions VI and VII are distinct and independent because they have different goals and are to be performed on separate patient populations; the methods of Invention VI are to be practiced on patients that are in need of increased cell growth, whereas the methods of Invention VII are to practiced on patients in need of decreased cell growth or inhibition of cell growth. Applicants are required to elect one of the Groups to be examined. Applicants respectfully request reconsideration of this restriction requirement for the following reasons.

Applicants respectfully disagree with restriction of the methods of Inventions I and II and the methods of Inventions IV and V based upon whether they can be performed in vitro or in vivo. The steps of these methods are identical and a search of the relevant prior art pertaining to the essential features of

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these steps can be made by the Examiner without serious burden. See MPEP 803.02. The courts have held that it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. In re Harnish, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Whether carried out in vitro or in vivo the methods of Inventions I and II and the methods of Inventions IV and V share the same essential elements and the same outcome. Therefore, no serious burden would be incurred by the Examiner in searching and examining the in vitro and in vivo methods together. Conversely, the prosecution of each of these inventions separately will pose substantial economic burden on Applicants. Thus, respectfully requested that this restriction requirement reconsidered.

However, in an earnest effort to be completely responsive, Applicants hereby elect to prosecute Group II, claim 46, drawn to in vivo methods of modulating cell growth, classified in class 514, subclass 12, for example.

Respectfully submitted,

January

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